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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/442,143	11/15/99	LEVY	G 9579-14

001059 HM12/0924
BERESKIN AND PARR
SCOTIA PLAZA
40 KING STREET WEST-SUITE 4000 BOX 401
TORONTO ON M5H 3Y2
CANADA AIR MAIL

EXAMINER	
NOLAN, P	
ART UNIT	**PAPER NUMBER**
1644	11

DATE MAILED: 09/24/01

09/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/442,143	Applicant(s) Levy et al.
	Examiner Patrick J. Nolan	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 28, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2-5 and 17* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2, 3, and 17* is/are rejected.

7) ☒ Claim(s) *4 and 5* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. This application is continuation of PCT/CA98/00475 application, filed May 15, 1998 which claims priority to provisional application 60/061684 filed October 10, 1997 and provisional applications 60/046,537 filed May 15, 1997.

2. Claims 2-5 and 17 are currently pending.

3. The specification stands objected to under 37 CFR 1.821(d) because the specification recites amino acid sequences and do not recite a proper sequence identifier. Figures 6-7 in the brief description of drawings, pages 4-5, for example) should include sequence identifiers adjacent referenced sequences. Applicants are required to include the appropriate SEQ ID NOs in the specification.

4. The following is a quotation of the first paragraph of 35 U.S.C. §112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

5. Claims 2, 3 and 17 stand rejected under 35 U.S.C.§ 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention, of record fore reasons set forth in Paper No. 8.

Applicant's arguments filed 6-28-01 have been fully considered but are not found persuasive.

Applicant argues the instantly claimed invention is limited to a single embodiment and therefore the *Regents of the University of California v. Eli Lilly & Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).* Is not relevant case law. However in order for one of skill in the art to practice the invention the full scope of the genus term Fgl2 needs to be considered. Fgl2 is not limited to human or murine derived Fgl2, but is instead open to Fgl2 derived from any source and so the Lilly case is relevant. Applicant has described the use of an antibody inhibitor to either mouse or human Flg2, i.e. SEQ ID NOS. 2

or 4. Applicant does not have sufficient written support for the use of any inhibitor to any Flg2 protein derived from an unlimited number of organisms.

Furthermore, Applicant is limited to the written description of anti-sense or antibodies to SEQ ID NO. 2 or 4 for the prevention or reduction of fetal loss. The scope of the term "inhibitor" is not adequately described by the description of two inhibitors, antibodies or anti-sense molecules.

In response to Applicant's arguments that other inhibitors of Flg2 were known prior to Applicant's disclosure, there description was not known for the reduction or prevention of fetal loss.

6. Applicant is notified that claims 4 and 5 are objected to as being dependent upon rejected claims.

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

9. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939.

Patrick J. Nolan

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
9/21/01